



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0227; FRL-8857-01-OCSP]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on pomegranate. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0227, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC

services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0227 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0227, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of September 30, 2020 (85 FR 61681) (FRL-10014-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8826) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The

petition requested to establish tolerances in 40 CFR 180.582 for residues of the sum of pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin, in or on the raw agricultural commodity pomegranate at 0.3 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyraclostrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclostrobin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target tissues following repeated pyraclostrobin exposure appear to be mucosal membranes, with histopathology or secondary effects (e.g., diarrhea) observed in different species. The primary effects were decreased body weight and food consumption in addition to diarrhea. There was no observed neurotoxicity, mutagenicity, genotoxicity, or immunotoxicity in the database. Also, there was no evidence of increased susceptibility following pre-natal exposure to rats and rabbits in the developmental toxicity studies, nor following pre- and post-natal exposure to rats in the multi-generation reproduction study. Pyraclostrobin is classified as “not likely to be carcinogenic to humans.”

Additional information on the toxicological profile can be found at <http://www.regulations.gov> in the document titled “Pyraclostrobin; Human Health Risk Assessment for a New Use on Pomegranate” (hereinafter “Pyraclostrobin Human Health Risk Assessment”) in docket ID number EPA-HQ-OPP-2020-0227.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure

(MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

A summary of the toxicological endpoints for pyraclostrobin used for human risk assessment can be found on pages 10-11 in the Pyraclostrobin Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraclostrobin tolerances in 40 CFR 180.582. EPA assessed dietary exposures from pyraclostrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for pyraclostrobin.

In conducting the acute dietary exposure assessment, EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). A partially refined acute dietary exposure assessment was conducted for pyraclostrobin. The analysis used tolerance-level residues or highest average field trial residues (HAFT) and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003-2008 food consumption data from the USDA's NHANES/WWEIA. A partially refined chronic dietary analysis was conducted for pyraclostrobin. The chronic dietary analysis included tolerance-level or average field trial residues and average PCT estimates when available.

iii. *Cancer*. Pyraclostrobin is classified as "Not Likely to Be Carcinogenic to Humans" therefore, a cancer assessment is not needed.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The following average PCT estimates were used in the chronic dietary risk assessments for the crops that are currently registered for pyraclostrobin: almonds 45%; apples 20%; apricots 30%; barley 10%; green beans 5%; blueberries 40%; broccoli 5%; Brussels sprouts 15%; cabbage 10%; caneberries 50%; cantaloupes 15%; carrots 35%; cauliflower 5%; celery 2.5%; cherries 55%; chicory 5%; corn 10%; cotton (seed treatment) 10%; cucumber 5%; dry beans/peas 10%; garlic 10%; grapefruit 35%; grapes 30%; hazelnuts 20%; lemons 5%; lettuce 5%; nectarines 15%; oats 5%; onions 30%; oranges 5%; peaches 25%; peanuts 20%; pears 20%; green peas 5%; pecans 5%; peppers 15%; pistachios 30%; potatoes 20%; pumpkins 15%; soybeans (seed treatment) 10%; spinach 5%; squash 15%; strawberries 65%; sugar beets 50%; sugarcane 5%; sweet corn 5%; tangerines 10%; tomatoes 25%; walnuts 10%; watermelons 25%; wheat 5%.

In most cases, EPA uses available data from United States Department of

Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyraclostrobin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water

exposure models in the dietary exposure analysis and risk assessment for pyraclostrobin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide in Water Calculator (PWC), for the acute dietary risk assessment, EPA used an estimated drinking water concentration (EDWC) of 22 ppb into the DEEM-FCID Model. For the chronic exposure assessment, EPA used a value of 0.99 ppb.

3. *Non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyraclostrobin is currently registered for uses that may result in residential handler and post-application exposures, including commercial and residential use on lawns, as well as commercial use on ornamental turf and trees, golf courses, and parks.

Based upon the hazard analysis for pyraclostrobin, short-term residential exposure that is available to be aggregated include incidental oral exposure (e.g., hand-to-mouth or object-to-mouth). Hand-to-mouth and object-to-mouth scenarios are considered inter-related, and it is likely that they occur interspersed amongst each other across time; combining these scenarios would be overly conservative. Residential short and intermediate-term dermal exposures (from children, youth, or adult scenarios) are not being combined with incidental oral exposure due to differing endpoints selected. Based upon the available scenarios, incidental oral (hand-to-mouth) exposures were used in the pyraclostrobin short-term aggregate assessment.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or

revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyraclostrobin and any other substances and pyraclostrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyraclostrobin has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the rat developmental toxicity study, skeletal variations occurred at doses greater than or equal to those doses causing maternal toxicity (i.e., diarrhea, decreased body weight, food consumption, and clinical signs of toxicity). In the rabbit developmental study, increased resorptions per litter, increased post-implantation loss, and dams with total resorptions were observed. Since the cause of fetal death is undetermined and may be attributed to either maternal or direct embryo fetal toxicity, the effect is part of both the maternal and developmental LOAEL. In one rat reproduction study, systemic toxicity manifested as decreased body weights in both the parents and offspring, with offspring effects occurring at a

higher dose level than parental toxicity. In the second rat reproduction study, no toxicity was observed in both parents and offspring. Therefore, there was no evidence of increased susceptibility (quantitatively) following pre-natal exposure to rats and rabbits in the developmental studies nor following pre- and post-natal exposure to rats in the multi-generation reproduction studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for pyraclostrobin is complete.
- ii. There are no indications in any of the studies available that the nervous system is a target for pyraclostrobin. In the absence of definitive neurotoxicity or neuropathology findings in the neurotoxicity battery or elsewhere in the database, a developmental neurotoxicity study is not required.
- iii. For the reasons summarized in section III.D.2, the degree of concern for prenatal and postnatal toxicity is low.
- iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure assessments were performed assuming 100 percent of the crops were treated with pyraclostrobin and incorporating tolerance-level or highest field trial residues. The chronic dietary exposure assessments were performed using average PCT estimates and tolerance-level or average field trial residues for crops in the screening level use analysis (SLUA), while 100 PCT was used for crops not included in the SLUA. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraclostrobin in drinking water. Although the acute and chronic assessments included minor refinements, the use of field trial and PCT estimates ensures that actual exposures/risks from residues in food will not be underestimated. Although some of the residue values used in the dietary exposure assessment were refined, these assessments will not underestimate the dietary exposure to

pyraclostrobin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to pyraclostrobin from food and water will utilize 86% of the aPAD for females 13 to 49 years old, the only population group of concern because no appropriate toxicological effect attributable to a single dose was observed for the general US population or any other population subgroup.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclostrobin from food and water will utilize 28% of the cPAD for all children 1 to 2 years old, the population group receiving the greatest exposure. Chronic residential exposure to residues of pyraclostrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Pyraclostrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pyraclostrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate

MOE of 430 for children 1 to 2 years old. Because EPA's level of concern for pyraclostrobin is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A separate intermediate-term adverse effect was identified for pyraclostrobin. However, pyraclostrobin is not registered for any use patterns that would result in intermediate-term residential exposures that can be combined with background dietary exposures. Because there is no intermediate-term residential aggregate exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD, no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for pyraclostrobin.

5. *Aggregate cancer risk for U.S. population.* Pyraclostrobin is classified as "Not Likely to Be Carcinogenic to Humans"; therefore, EPA does not expect pyraclostrobin exposures to pose an aggregate cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyraclostrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two adequate methods are available for enforcement purposes for residues of pyraclostrobin and its metabolites in/on plant commodities: a liquid chromatography with tandem mass spectroscopy (LC/MS/MS) method (BASF Method D9908) and a high-performance liquid chromatography/ultraviolet (HPLC/UV) method (Method D9904).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with

international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4).

There is no Codex MRL for pyraclostrobin in or on pomegranate.

V. Conclusion

Therefore, a tolerance is established for residues of pyraclostrobin in or on pomegranate at 0.3 ppm. Additionally, the Agency is putting back a footnote that states “There is no U.S. registration on coffee, bean, green as of September 30, 2009” to the table in paragraph (a)(1) that was inadvertently removed in 2013.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.),

do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 13, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.582, amend the table in paragraph (a)(1) by adding in alphabetical order the commodity “Pomegranate” and a footnote 1 at the end of the table to read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	*
Pomegranate	0.3
* * * * *	*

¹ There is no U.S. registration on coffee, bean, green as of September 30, 2009.

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